



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2019-0237; FRL-9283-03-OCSPP]

Cyclic Aliphatic Bromide Cluster (HBCD); Revision to the Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of the final revision to the risk determination for the Cyclic Aliphatic Bromide Cluster (HBCD) risk evaluation issued under the Toxic Substances Control Act (TSCA). The revision to the HBCD risk determination reflects the announced policy changes to ensure the public is protected from unreasonable risks from chemicals in a way that is supported by science and the law. EPA determined that HBCD, as a whole chemical substance, presents an unreasonable risk of injury to health and the environment when evaluated under its conditions of use. In addition, this revised risk determination does not reflect an assumption that all workers always appropriately wear personal protective equipment (PPE). EPA understands that there could be occupational safety protections in place at workplace locations; however, not assuming use of PPE reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, or their employers are out of compliance with OSHA standards, or because OSHA has not issued a permissible exposure limit (PEL) (as is the case for HBCD). This revision supersedes the condition of use-specific no unreasonable risk determinations in the September 2020 HBCD risk evaluation and withdraws the associated order included in section 5.4.1 of the September 2020 HBCD risk evaluation.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2019-0237, is available online at <https://www.regulations.gov> or in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket) in the Environmental

Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Alie Muneer, Office of Pollution Prevention and Toxics (7404T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-6369; email address: muneer.alie@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to those involved in the manufacture, processing, distribution, use, disposal, and/or the assessment of risks involving chemical substances and mixtures. You may be potentially affected by this action if you manufacture (defined under TSCA to include import), process (including recycling), distribute in commerce, use or dispose of HBCD, including HBCD in products. Since other entities may also be interested in this revision to the risk determination, EPA has not attempted to describe all the specific entities that may be affected by this action.

B. What is EPA's authority for taking this action?

TSCA section 6, 15 U.S.C. 2605, requires EPA to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the

environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation (PESS) identified as relevant to the risk evaluation by the Administrator, under the conditions of use. 15 U.S.C. 2605(b)(4)(A). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that provide instruction on chemical substances that must undergo evaluation, the minimum components of a TSCA risk evaluation, and the timelines for public comment and completion of the risk evaluation. TSCA also requires that EPA operate in a manner that is consistent with the best available science, make decisions based on the weight of the scientific evidence and consider reasonably available information. 15 U.S.C. 2625(h), (i), and (k).

The statute identifies the minimum components for all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C. 2605(b)(4)(D). The statute further provides that each risk evaluation must also: (1) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on relevant potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposures. 15 U.S.C. 2605(b)(4)(F)(i) through (ii) and (iv) through (v). Each risk evaluation must not consider costs or other nonrisk factors. 15 U.S.C. 2605(b)(4)(F)(iii).

EPA has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision to the extent permitted by law and supported by reasoned explanation. *FCC v.*

Fox Television Stations, Inc., 556 U.S. 502, 515 (2009); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Further, on August 10, 2021, the Ninth Circuit granted EPA's motion for voluntary remand without vacatur, so that EPA may conduct reconsideration proceedings on the HBCD Risk Evaluation—particularly to reconsider the no unreasonable risk determinations made within. *Alaska Community Action on Toxics et al., v. U.S. Environmental Protection Agency et al.*, (9th Cir. No. 20-73099).

C. What action is EPA taking?

EPA is announcing the availability of the final revision to the risk determination for the HBCD risk evaluation issued under TSCA that published in September 2020. In December 2021, EPA sought public comment on the draft revisions (86 FR 74082, December 29, 2021 (FRL-9283-01-OCSPP)) and reopened the comment period for an additional 15 days (87 FR 9047, February 17, 2022 (FRL-9283-02-OCSPP)). EPA appreciates the public comments received on the draft revision to the HBCD risk determination. After review of these comments and consideration of the specific circumstances of HBCD, EPA concludes that the Agency's risk determination for HBCD is better characterized as a whole chemical risk determination rather than condition-of-use-specific risk determinations. Accordingly, EPA is revising and replacing section 5 of the 2020 risk evaluation for HBCD where the findings of unreasonable risk to health and the environment were previously made for the individual conditions of use evaluated. EPA is also withdrawing the previously-issued TSCA section 6(i)(1) order for six conditions of use previously determined not to present unreasonable risk that was included in section 5.4.1 of the September 2020 HBCD risk evaluation.

This final revision to the HBCD risk determination is consistent with EPA's plans to revise specific aspects of the first ten TSCA chemical risk evaluations to ensure that the risk evaluations better align with TSCA's objective of protecting health and the environment. The six conditions of use identified in the 2020 HBCD risk evaluation as presenting unreasonable risk still drive the unreasonable risk determination for HBCD. By removing the assumption that all

workers always and appropriately wear PPE (See Unit II.C.), four of the six conditions of use driving the unreasonable risk to the environment in the 2020 HBCD risk evaluation now also drive unreasonable risk based on health risks to workers, an identified potentially exposed or susceptible subpopulation (PESS). The four conditions of use affected by this change are: Manufacturing (Import); Processing: Incorporation into formulation, mixture, or reaction products; Processing: Incorporation into articles; and Processing: Recycling (of XPS and EPS foam, resin, panels containing HBCD). Overall, six conditions of use drive the HBCD whole chemical unreasonable risk determination due to risks identified for both health and the environment. The full list of the conditions of use evaluated for the HBCD TSCA risk evaluation is in Table 1-8 of the risk evaluation available here https://www.epa.gov/sites/default/files/2020-09/documents/1._risk_evaluation_for_cyclic_aliphatic_bromide_cluster_hbcd_casrn25637-99-4_casrn_3194-5_casrn_3194-57-8.pdf.

II. Background

A. Why is EPA re-issuing the risk determination for the HBCD risk evaluation conducted under TSCA?

In accordance with Executive Order 13990 (Ref. 1) and other Administration priorities (Refs. 2, 3, and 4), EPA reviewed the risk evaluations for the first ten chemical substances, including HBCD, to ensure that they meet the requirements of TSCA, including conducting decision-making in a manner that is consistent with the best available science.

As a result of this review, EPA announced plans to revise specific aspects of the first ten risk evaluations in order to ensure that the risk evaluations appropriately identify unreasonable risks and thereby help ensure the protection of human health and the environment (available here <https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations>). Following a review of specific aspects of the September 2020 HBCD risk evaluation and after considering comments received on a draft revised risk determination for HBCD, EPA has determined that making an unreasonable risk determination for HBCD as a

whole chemical substance, rather than making unreasonable risk determinations separately on each individual condition of use evaluated in the risk evaluation, is the most appropriate approach to HBCD under the statute and implementing regulations. Second, EPA's final risk determination is explicit insofar as it does not rely on assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determination under TSCA section 6, even though some facilities might be using PPE as one means to reduce workers exposures; rather, the use of PPE as a means of addressing unreasonable risk will be considered during risk management, as appropriate.

This action pertains only to the risk determination for HBCD. While EPA intends to consider and may take additional similar actions on other of the first ten chemicals, EPA is taking a chemical-specific approach to reviewing these risk evaluations and is incorporating new policy direction in a surgical manner, while being mindful of Congressional direction on the need to complete risk evaluations and move toward any associated risk management activities in accordance with statutory deadlines.

B. What is a whole chemical view of the unreasonable risk determination for the HBCD risk evaluation?

TSCA section 6 repeatedly refers to determining whether a chemical *substance* presents unreasonable risk under its conditions of use. Stakeholders have disagreed over whether a chemical substance should receive: A single determination that is comprehensive for the chemical substance after considering the conditions of use, referred to as a whole-chemical determination; or multiple determinations, each of which is specific to a condition of use, referred to as condition-of-use-specific determinations.

As explained in the *Federal Register* document announcing the availability of the draft revised risk determination for HBCD (86 FR 74082, December 29, 2021 (FRL-9283-01-OCSPP), the proposed Risk Evaluation Procedural Rule (Ref. 5) was premised on the whole chemical approach to making unreasonable risk determinations. In that proposed rule, EPA

acknowledged a lack of specificity in statutory text that might lead to different views about whether the statute compelled EPA's risk evaluations to address all conditions of use of a chemical substance or whether EPA had discretion to evaluate some subset of conditions of use (i.e., to scope out some manufacturing, processing, distribution in commerce, use, or disposal activities) , but also stated that "EPA believes the word "the" (in TSCA section 6(b)(4)(A)) is best interpreted as calling for evaluation that considers all conditions of use." The proposed rule, however, was unambiguous on the point that unreasonable risk determinations would be for the chemical substance as a whole, even if based on a subset of uses. See Ref. 5 at 7565-66 ("TSCA section 6(b)(4)(A) specifies that a risk evaluation must determine whether 'a chemical substance' presents an unreasonable risk of injury to health or the environment 'under the conditions of use.' The evaluation is on the chemical substance—not individual conditions of use—and it must be based on 'the conditions of use.' In this context, EPA believes the word 'the' is best interpreted as calling for evaluation that considers all conditions of use."). In proposed regulatory text, EPA proposed to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use. Ref. 5 at 7480.

The final Risk Evaluation Procedural Rule stated (82 FR 33726, July 20, 2017 (FRL-9964-38)) (Ref. 6): "As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents" (40 CFR 702.47). For the unreasonable risk determinations in the first ten risk evaluations, EPA applied this provision by making individual risk determinations for each condition of use evaluated as part of each risk evaluation document (i.e., the condition-of-use-specific approach to risk determinations). That approach was based on one particular passage in the preamble to the final Risk Evaluation Rule "which stated that EPA will make individual risk determinations for all conditions of use identified in the scope. (Ref. 6 at 33744)."

In contrast to this portion of the preamble of the final Risk Evaluation Rule, the regulatory text itself and other statements in the preamble reference a risk determination *for the chemical substance* under its conditions of use, rather than separate risk determinations for each of the conditions of use of a chemical substance. In the key regulatory provision excerpted previously from 40 CFR 702.47, the text explains that, “[a]s part of the risk evaluation, EPA will determine whether *the chemical substance* presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents” (emphasis added). Other language reiterates this perspective. For example, 40 CFR 702.31(a) states that the purpose of the rule is to establish the EPA process for conducting a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B). Likewise, there are recurring references to whether the chemical substance presents an unreasonable risk in 40 CFR 702.41(a). See, for example, 40 CFR 702.41(a)(6), which “[e]xplains that the extent to which EPA will refine its evaluations for one or more condition of use in any risk evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk.” Notwithstanding the one preambular statement about condition-of-use-specific risk determinations, the preamble to the final rule also contains support for a risk determination on the chemical substance as a whole. In discussing the identification of the conditions of use of a chemical substance, the preamble notes that this task inevitably involves the exercise of discretion on EPA’s part, and, “as EPA interprets the statute, the Agency is to exercise that discretion consistent with the objective of conducting a technically sound, manageable evaluation to determine whether a chemical substance—not just individual uses or activities—presents an unreasonable risk” (Ref. 6 at 33729).

Therefore, notwithstanding EPA’s choice to issue condition-of-use-specific risk determinations to date, EPA interprets its risk evaluation regulation to also allow the Agency to issue whole-chemical risk determinations. Either approach is permissible under the regulation. A

panel of the Ninth Circuit Court of Appeals also recognized the ambiguity of the regulation on this point. *Safer Chemicals v. EPA*, 943 F.3d. 397, 413 (9th Cir. 2019) (holding a challenge about “use-by-use risk evaluations [was] not justiciable because it is not clear, due to the ambiguous text of the Risk Evaluation Rule, whether the Agency will actually conduct risk evaluations in the manner Petitioners fear”).

EPA plans to consider the appropriate approach for each chemical substance risk evaluation on a case-by-case basis, taking into account considerations relevant to the specific chemical substance in light of the Agency’s obligations under TSCA. The Agency expects that this case-by-case approach will provide greater flexibility in the Agency’s ability to evaluate and manage unreasonable risk from individual chemical substances. EPA believes this is a reasonable approach under TSCA and the Agency’s implementing regulations.

With regard to the specific circumstances of HBCD, EPA has determined that a whole chemical approach is appropriate for HBCD in order to protect health and the environment. The whole chemical approach is appropriate for HBCD because there are benchmark exceedances for multiple conditions of use (spanning across most aspects of the chemical lifecycle—from manufacturing (import), processing, commercial use, and disposal) for both health and the environment, HBCD is persistent, bioaccumulative and toxic substance, and the health effects associated with HBCD exposures are irreversible. Because these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, a substantial amount of the conditions of use drive the unreasonable risk, therefore it is appropriate for the Agency to make a determination for HBCD, EPA has concluded that the whole chemical presents an unreasonable risk.

As explained later in this document, the revisions to the unreasonable risk determination (section 5 of the risk evaluation) follow the issuance of a draft revision to the TSCA HBCD unreasonable risk determination (86 FR 74082, December 29, 2021) and the receipt of public comment. A response to comments document is also being issued with this final revised

unreasonable risk determination for HBCD. The revisions to the unreasonable risk determination are based on the existing risk characterization section of the risk evaluation (Section 4 of the risk evaluation) and do not involve additional technical or scientific analysis. The discussion of the issues in this *Federal Register* document and in the accompanying final revised risk determination for HBCD supersede any conflicting statements in the prior HBCD risk evaluation and the earlier response to comments document (Ref. 9). EPA views the peer reviewed hazard and exposure assessments and associated risk characterization as robust and upholding the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i).

For purposes of TSCA section 6(i), EPA is making a risk determination on HBCD as a whole chemical. Under the revised approach, the “whole chemical” risk determination for HBCD supersedes the no unreasonable risk determinations for HBCD that were premised on a condition-of-use-specific approach to determining unreasonable risk and also contains an order withdrawing the TSCA section 6(i)(1) order in section 5.4.1 of the September 2020 HBCD risk evaluation.

C. What revision is EPA now making final about the use of PPE for the HBCD risk evaluation?

In the risk evaluations for the first ten chemical substances, as part of the unreasonable risk determination, EPA assumed for several conditions of use that all workers were provided and always used PPE in a manner that achieves the stated assigned protection factor (APF) for respiratory protection, or used impervious gloves for dermal protection. In support of this assumption, EPA used reasonably available information such as public comments indicating that some employers, particularly in the industrial setting, provide PPE to their employees and follow established worker protection standards (e.g., Occupational Safety and Health Administration (OSHA) requirements for protection of workers).

For the September 2020 HBCD risk evaluation, EPA assumed that workers used PPE for six of the twelve conditions of use:

- Manufacturing - Import;
- Processing: Incorporating into formulation, mixture, or reaction products;
- Processing: Incorporation into article;
- Processing: Recycling (of XPS and EPS foam, resin, panels containing HBCD);
- Processing: Recycling (of electronics waste containing high impact polystyrene (HIPS)

that contains HBCD); and

- Commercial/Consumer Use: Other – Formulated Products and Articles

EPA is revising the assumption for HBCD that workers always or properly use PPE, although it does not question the public comments received regarding the occupational safety practices often followed by industry respondents. When characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place. This approach considers the risk to potentially exposed or susceptible subpopulations of workers who may not be covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan.

In addition, EPA believes it is appropriate to evaluate the levels of risk present in scenarios considering applicable OSHA requirements (e.g., chemical-specific permissible exposure limits (PELs) and/or chemical-specific PELs with additional substance-specific standards), as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. Consistent with this approach, the September 2020 HBCD risk evaluation characterized risk to workers both with and without the use of PPE. By characterizing risks using scenarios that reflect different levels of mitigation, EPA risk evaluations can help inform potential risk management actions by providing information that

could be used during risk management to tailor risk mitigation appropriately to address any unreasonable risk identified, or to ensure that applicable OSHA requirements or industry or best sector practices that address the unreasonable risk are required for all potentially exposed and susceptible subpopulations of workers (including self-employed individuals and public sector workers who are not covered by an OSHA State Plan).

When undertaking unreasonable risk determinations as part of TSCA risk evaluations, however, EPA does not believe it is appropriate to assume as a general matter that an applicable OSHA requirement or industry practice is consistently and always properly applied. Mitigation scenarios included in the EPA risk evaluation (e.g., scenarios considering use of various PPE) likely represent what is happening already in some facilities. However, the Agency cannot assume that all facilities have adopted these practices for the purposes of making the TSCA risk determination.

Therefore, EPA is making a determination of unreasonable risk for HBCD from a baseline scenario that does not assume compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE. Making unreasonable risk determinations based on the baseline scenario should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread non-compliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements.

In accordance with this approach, EPA is finalizing the revision to the HBCD risk determination without relying on assumptions regarding the occupational use of PPE in making the unreasonable risk determination under TSCA section 6; rather, information on the use of PPE

as a means of mitigating risk (including public comments received from industry respondents about occupational safety practices in use) will be considered during the risk management phase, as appropriate. This represents a change from the approach taken in the 2020 risk evaluation for HBCD. As a general matter, when undertaking risk management actions, EPA intends to strive for consistency with applicable OSHA requirements and industry best practices, including appropriate application of the hierarchy of controls, to the extent that applying those measures would address the identified unreasonable risk, including unreasonable risk to potentially exposed or susceptible subpopulations. Consistent with TSCA section 9(d), EPA will consult and coordinate TSCA activities with OSHA and other relevant Federal agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements. Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules that require risk management practices that may be already common practice in many or most facilities. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers, especially in cases where current OSHA standards may not apply or be sufficient to address the unreasonable risk.

By removing the assumption of PPE use in making the whole chemical risk determination for HBCD, the same six conditions of use would continue to drive the proposed unreasonable risk determination. However, the impact of removing the assumption of PPE use would cause four of the six conditions of use that drive the unreasonable risk determination based on only risks to the environment to also drive unreasonable risk based on health risks to workers. The four conditions of use affected by this change are:

- Manufacturing - Import;
- Processing: Incorporation into formulation, mixture, or reaction products;
- Processing: Incorporation into article; and
- Processing: Recycling (of XPS and EPS foam, resin, panels containing HBCD).

D. What is HBCD?

HBCD is a white odorless non-volatile solid that is used as a flame retardant and wetting agent. Domestic manufacture of HBCD ceased in 2017 and was therefore not considered as a condition of use for the risk evaluation. U.S. manufacturers have indicated complete replacement of HBCD in their product lines and that depletion of stockpiles and cessation of export was completed in 2017 based on communications with manufacturers. HBCD has also not been imported by any major importers since 2017; however, it is reasonably foreseen that small imports under the TSCA Chemical Data Reporting threshold may have continued from countries that were not parties to the Stockholm Convention ban. About 95% of HBCD was historically used in insulation boards, primarily in construction materials, which may include structural insulated panels (SIPS). The category “Building/Construction Materials” includes products containing HBCD as a flame retardant primarily in XPS and EPS rigid foam insulation products that are used for the construction of residential, public, commercial, or other structures. HBCD is added to XPS and EPS foam in the form of a resin. EPS foam prevents freezing, provides a stable fill material, and creates high-strength composites in construction applications. XPS foam board is used mainly for roofing applications and architectural molding. Minor uses of HBCD include replacement car parts (polystyrene headliners and solder) and solder paste for electronics (circuit boards). Historically, HBCD was also manufactured (including import) and processed for additional articles that may still exist, including adhesives, coatings, sealants, textiles, and electronics.

E. What conclusions is EPA finalizing today in the revised TSCA risk evaluation based on the whole chemical approach and not assuming the use of PPE?

EPA determined that HBCD presents an unreasonable risk to health and the environment under the conditions of use. EPA’s unreasonable risk determination for HBCD is driven by risks associated with the following conditions of use, considered singularly or in combination with other exposures:

- Manufacturing - Import;
- Processing: Incorporation into a Formulation, Mixture, or Reaction Products;
- Processing: Incorporation into Article;
- Processing: Recycling (of XPS and EPS foam, resin, and panels containing HBCD);
- Commercial/Consumer Use: Building/Construction Materials (Installation); and
- Disposal (Demolition).

Note: While commercial and consumer use was assessed as part of the same exposure scenario for the “Commercial/Consumer Use: Building/Construction Materials (Installation)” condition of use, risks were quantified separately, and consumer use was not found to drive the HBCD unreasonable risk.

III. Summary of Public Comments

EPA received a total of 25 public comments on the December 29, 2021, draft revised risk determination for HBCD during the initial and extended comment period from December 29, 2021 to March 4, 2022. Commenters included trade organizations, trade unions, industry stakeholders, environmental groups, a Tribal organization, and non-governmental and health advocacy organizations. A separate document that summarizes all comments submitted and EPA’s responses to those comments has been prepared and is available in the docket for this notice (Ref. 7).

A. General comments in support of and opposed to the revised risk determination.

Several commenters supported the HBCD revised unreasonable risk determination because the whole chemical approach better aligns with the goals of TSCA and the 2016 Lautenberg amendments. In addition, commenters noted that by removing the assumption that workers always and appropriately wear PPE, EPA can better protect workers and potentially exposed and sensitive subpopulations (PESS). Those commenters who opposed the revised risk determination indicated concerns with unwarranted impacts relating to expected risk management regulatory decisions, including on articles and associated supply chains.

EPA Response: EPA appreciates the support for the revised unreasonable risk determination. With respect to impacts relating to expected risk management regulation of HBCD, EPA will propose a regulatory action with requirements under TSCA section 6(a) to the extent necessary so that HBCD no longer presents unreasonable risk. The proposed risk management rule will be subject to public comments, and EPA will consider such public comments and any additional reasonably available information before finalizing the rulemaking, including information related to potential impacts to supply chains and HBCD-containing articles.

B. General legal issues.

A commentor indicated that EPA should use its authority under TSCA to research and collect additional occupational exposure data, while other commentors indicated that the revised unreasonable risk determination does not comply with TSCA section 26 scientific requirements and should be updated to reflect EPA's 2021 Draft Systematic Review protocol.

The second major topic of legal concern raised was whether EPA can revise the HBCD risk determination prior to undertaking a notice and comment rulemaking to revise the final Risk Evaluation Rule (*Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, July 20, 2017)). In the view of commenters, the final Risk Evaluation Rule, allows EPA to assess risk and promulgate rules that would apply only to the conditions of use that present unreasonable risk. Several commenters took issue with EPA's new interpretation of the final Risk Evaluation Rule, stating that the rule lacks the ambiguity necessary to permit a court to grant *Auer* deference to the EPA's regulatory interpretation. In other words, the commenters claim the final Risk Evaluation Rule unequivocally requires EPA to make determinations for each condition of use and those conditions of use which do not present unreasonable risk would not be subject to risk management. Commenters indicated that EPA should not be permitted *Auer* deference with respect to its regulatory interpretation but rather must engage in a separate rulemaking with notice and comment to revise that regulation before

engaging in the whole chemical approach to risk determination.

A third point raised was by a commenter that indicated that EPA did not fix existing legal flaws in the final risk evaluation, since EPA did not evaluate risk to all relevant subpopulations, including Alaska Indigenous Peoples, firefighters, and infants.

EPA Response: EPA identified and reviewed occupational exposure information through the systematic review process and from public commenters to inform the HBCD risk evaluation. EPA considers that information relied on in the risk evaluation, as reflected in the hazard and exposure assessments and risk characterization in the September 2020 risk evaluation, to be sufficient on occupational exposure to make the unreasonable risk determination and inform risk management. While EPA is undertaking efforts to refine its 2018 approach to systematic review, the draft protocol is not yet final. EPA expects to apply that protocol, when final, prospectively and not retroactively; retroactive application would lead to further delays in completing the risk evaluations for the first ten substances and associated risk management activities, contrary to Congressional intent. Thus, EPA maintains that the 2020 HBCD risk evaluation meets TSCA section 26(h) requirements. EPA welcomes any additional information from stakeholders during the development of the HBCD risk management rule; however, EPA expects to be able to complete a proposed and final risk management rule without additional information regarding occupational exposures to HBCD.

EPA has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision to the extent permitted by law and supported by reasoned explanation. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); see also *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). As to the final Risk Evaluation Rule, EPA acknowledges a lack of specificity in the statute and inconsistency in the regulations with respect to the presentation of risk determinations in TSCA section 6 risk evaluations. Notwithstanding EPA's choice to issue condition-of-use-specific risk determinations to date, EPA interprets its risk evaluation regulation to also allow the Agency to issue whole-

chemical risk determinations. Either approach is permissible under the regulation, and the Agency's interpretation is entitled to *Auer* deference when using the multifactor test set forth in *Kisor* (See Ref. 7). As such, notice and comment rulemaking is not necessary before revising the HBCD risk determination.

As a general matter, EPA must apply one or more requirements in TSCA section 6(a) to the extent necessary to address the unreasonable risk determined to be presented through a TSCA section 6(b) risk evaluation. Under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management options related to manufacture, processing, distribution in commerce, commercial use, and disposal in order to address the unreasonable risk. For instance, EPA may regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities driving unreasonable risk (e.g., consumer use) even if the upstream activities do not themselves drive the unreasonable risk.

As explained in Ref. 9, EPA incorporated aggregate exposures covering all potential exposure routes for the general population and consumers in the final risk evaluation and the revised unreasonable risk determination. In addition, infants and subsistence fishers are identified as potentially exposed or susceptible subpopulations (PESS) and risks are reflected in the final risk evaluation. Finally, EPA explained how exposures to firefighters were considered and acknowledges that firefighter exposure to HBCD is an uncertainty in the risk evaluation (see Section 2.4.1.15.5 of the Risk Evaluation).

C. Revisions to the risk determination – whole chemical approach vs. individual conditions of use.

As mentioned previously, several commenters supported the whole chemical approach on the basis that TSCA requires EPA to identify the full risk posed by a chemical substance. One commenter believes TSCA requires whole chemical determinations of unreasonable risk to satisfy the mandate to integrate and assess available information on hazards and exposures from

the condition of use, especially in cases of potentially exposed or susceptible subpopulations, multiple routes of exposure, and combined risk to exposed populations across the chemical's conditions of use and life-cycle stages. Others questioned whether EPA had the authority to change the risk determination to a whole chemical approach and whether this change was appropriate for HBCD. Some commenters opposed the whole chemical approach because the scope of the risk evaluation was based on conditions of use. In addition, some commenters indicated that EPA does not provide support for a whole chemical unreasonable risk determination given that certain conditions of use pose no unreasonable risk and a whole chemical approach would lump together uses that do not present unreasonable risk with those that do. Furthermore, the commenter noted that EPA has not explained why a majority of conditions of use should trigger a whole chemical unreasonable risk determination, EPA has not provided criteria for when to take a whole chemical approach, and manufacturers will no longer have incentives to request risk evaluations. In addition, some commenters requested that EPA review the whole chemical approach in the context of the risk management rules, how this approach would affect risk management, the need to clarify the intended practical and legal implications of this new approach, and how the implementation of the whole chemical approach is consistent with the best available science and the weight of the scientific evidence.

EPA Response: The whole chemical approach is appropriate for HBCD because there are benchmark exceedances for multiple conditions of use (spanning across most aspects of the chemical lifecycle—from manufacturing (import), processing, commercial use, and disposal) for both health and the environment, HBCD is a persistent, bioaccumulative and toxic substance, and the health effects associated with HBCD exposures are irreversible. Because these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, a substantial amount of the conditions of use drive the unreasonable risk, therefore it is appropriate for the Agency to make a determination that the whole chemical presents an unreasonable risk. The revised unreasonable risk determination for HBCD reflects EPA's objective of conducting a

technically sound, manageable evaluation to determine whether the chemical substance — not just individual uses or activities — presents an unreasonable risk.

Responding to comments about conditions of use which previously were found to not present unreasonable risk for HBCD, in the final revised risk determination, EPA identifies the conditions of use that drive the unreasonable risk of HBCD. Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management regulatory actions to the extent necessary so that HBCD no longer presents an unreasonable risk. Therefore, it is expected that EPA's risk management action likely will focus on the conditions of use that drive the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. For example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities driving unreasonable risk (e.g., consumer use) even if the upstream activities do not drive the unreasonable risk. The public will have an opportunity to provide comments and any additional information during the comment period for the proposed risk management rule. In the case of manufacturer-request risk evaluation (MRRE), EPA has the ability to add conditions of use to the MRRE and it is possible that only some conditions of use will drive the unreasonable risk. EPA is mindful of this reality and intends to continue to be transparent during the risk evaluation and when making an unreasonable risk determination for the chemical substance as a whole to articulate which conditions of use drive the unreasonable risk and which do not. Also, EPA will continue to carry out analysis of the conditions of use within the scope of the risk evaluation and conduct risk management rulemaking to address any identified unreasonable risk.

EPA considers the risk characterization, including hazard and exposure to HBCD, included in the September 2020 risk evaluation to account for reasonably available information

for HBCD, and does not intend to amend the underlying scientific analysis in the risk characterization section of the risk evaluation. EPA also views the peer reviewed hazard and exposure assessments and associated risk characterization as robust and upholding the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i).

D. Revisions to the risk determination – Assumptions of use of Personal Protective Equipment (PPE).

Some commenters supported EPA's decision to no longer rely on the assumption that workers always and properly use PPE when evaluating exposures in a risk evaluation. In their view, EPA needs to evaluate industry practices and EPA cannot assume that OSHA regulations will effectively require that workers always and appropriately use PPE. A commenter noted that the assumption of the use of PPE is not sufficiently supported by the practical realities of many workplaces. A commentor indicated that industry best practices are not relevant in determining whether regulations are needed to protect workers, and voluntary efforts can disappear in an instant, in a workplace or across a whole industry, and that regulation is thus needed to protect employees. Other commenters expressed opposition to EPA's intention not to assume PPE is always and properly used when conducting risk evaluations. For example, several commenters stated that EPA's decision not to assume the use of PPE is inconsistent with the definition of conditions of use under TSCA and contravenes TSCA's explicit requirement under TSCA section 26(k) to take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator. Some commentors stated that EPA's proposed approach would artificially increase the calculated human health risk for particular uses of a chemical and create a false and misleading perception of worker risk. A couple of commentors suggested that EPA continue the approach of presenting both scenarios – HBCD use with and without PPE – to provide the appropriate bounding scenarios for HBCD risk exposures in the workplace. Another commentor added that it would also be appropriate for EPA to review and revise its modeling

assumptions to ensure they reflect the state-of-the-art facilities and current industry practices. A commenter indicated that the discussion regarding industrial hygiene was imprecise and it is not clear if EPA intends to make unreasonable risk determinations from a baseline scenario that does not assume compliance with OSHA standards or the entire industrial hygiene hierarchy of controls. Several commentors encouraged EPA to coordinate and engage with OSHA. Finally, there were several comments regarding EPA's use of the OSHA particulates not otherwise regulated (PNOR) permissible exposure limit (PEL) to HBCD as an exposure limit reference to workers engaged in demolition and disposal of XPS and EPS foam insulation. A commenter provided specific examples of the controls that are utilized on jobsites to comply with OSHA requirements and minimize worker exposure to dust and other particulate matter.

EPA Response: EPA believes it is appropriate to evaluate the levels of risk present in scenarios considering applicable OSHA requirements as well as scenarios considering industry or sector best practices for industrial hygiene because such evaluation can help inform potential risk management actions (i.e., by informing EPA's assessment of the feasibility and efficacy of different risk management options). However, EPA cannot reasonably assume that all facilities will have adopted these practices. Therefore, EPA is making its determination of unreasonable risk from a baseline scenario that does not assume compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE. This reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, or because their employer is out of compliance with OSHA standards, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements. In accordance with TSCA section 26(k), EPA considers reasonably available information, including information on occupational controls and PPE usage, when conducting TSCA section 6 risk evaluations and risk management rules.

Under TSCA section 6(a), EPA must apply one or more risk management requirements to

the extent necessary so that a chemical substance no longer presents unreasonable risk. Those requirements may include restrictions on the manufacture, processing, distribution in commerce, commercial use, or disposal of a chemical substance. Because the requirements and application of TSCA and OSHA regulatory analyses differ, it is appropriate that EPA conduct risk evaluations and, where it finds unreasonable risk to workers, develop risk management requirements for chemical substances that OSHA also regulates, and it is expected that EPA's findings and requirements may sometimes diverge from OSHA's. However, it is also appropriate that EPA consider the standards that OSHA has already developed, so as to limit the compliance burden to employers by aligning management approaches required by the agencies, where alignment will adequately address unreasonable risk to workers. Consistent with TSCA section 9(d), EPA will consult and coordinate TSCA activities with OSHA and other relevant federal agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements. Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules that require risk management practices that may already be common practice in many or most facilities, including those mentioned by the commenters regarding controls used in demolition and disposal of XPS and EPS foam insulation. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers, especially in cases where current OSHA standards may not apply or be sufficient to address the unreasonable risk.

The revised unreasonable risk determination for HBCD is based on the underlying risk assessments and risk characterization, in which EPA evaluated worker risk with and without PPE, and which were peer-reviewed by the Science Advisory Committee on Chemicals (SACC). EPA considers the risk characterization, including hazard and exposure to HBCD, included in the September 2020 risk evaluation to account for reasonably available information for HBCD, including reasonably available information regarding state-of-the-art facilities and current

industry practices. Section 4.5.1 and Table 4-27 of the final risk evaluation summarizes the peer reviewed risk estimates without PPE and informed the revised unreasonable risk determination.

As previously addressed by the Agency in Ref. 9, the OSHA PNOR PEL model was used in the absence of relevant data for the Demolition and Disposal of XPS and EPS Foam Insulation in Residential, Public, and Commercial Buildings, and Other Structures.

E. Conditions of use that drive the unreasonable risk determination.

A commenter expressed concern that in the 2020 Risk Evaluation EPA concluded that the consumer/commercial use of HBCD in articles does not pose an unreasonable risk, but by taking a whole chemical approach, EPA's action may foster public perception that these COUs present an unreasonable risk. Another commenter said that EPA should use a Significant New Use Rule (SNUR) to confirm cessation of current use and prevent new uses of HBCD without review and assent by the EPA. One commenter said that data on the recycling of old EPS building insulation indicates that it is not being recycled in a manner that would result in a finding of unreasonable risk; and another commenter suggested that EPA isolate materials containing HBCD and direct them to proper disposal. A commenter further indicated that the finding of demolition of EPS insulation to present an unreasonable risk is based on inaccurate assumptions and provided similar information to comments received during the risk evaluation. Another commenter cautioned against EPA imposing additional duplicative requirements or regulatory burdens, such as existing stormwater controls. In a similar vein, a commenter said that the models used to support the unreasonable risk determination for demolition of buildings with HBCD era EPS over-estimated the amount of HBCD; conversely, another commenter stated that EPA ignored the risk caused by the disposal of HBCD, particularly the vast quantities of insulation sent to landfills and incinerators, which resulted in an underestimation of the risk HBCD.

EPA Response: Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management requirements to the extent necessary so that HBCD no longer presents an unreasonable risk. Under TSCA section 6(a), EPA is not limited to regulating the

specific activities found to drive unreasonable risk and may select from among a suite of risk management options related to manufacture, processing, distribution in commerce, commercial use, and disposal in order to address the unreasonable risk. EPA's authority under TSCA section 6(a) is not affected by the change to a whole chemical risk determination for HBCD. Processing: Incorporation into Articles is one of the conditions of use that drives the HBCD unreasonable risk and will be subject to risk management action. EPA will undertake a separate public notice and comment period as part of the TSCA section 6(a) risk management rulemaking for HBCD, and will consider such public comments and any additional information before finalizing the rulemaking. EPA acknowledges the commenter's suggestions related to storm water control requirements and risk management of HBCD, and encourages the commenter to submit specific comments along these lines during the future public comment period for the HBCD risk management rule.

EPA appreciates the suggestion to promulgate a SNUR to confirm cessation of current uses and prevent new uses of HBCD from commencing without notification to and review by the Agency; however, given international commitments and anticipated impacts of TSCA section 6(a) risk management rulemaking for HBCD, it is unlikely that past practices or new uses of HBCD would be initiated.

With respect to the specific comments regarding recycling and disposal, EPA originally presented the underlying scientific analysis in the draft risk evaluation released in July 2019 (84 FR 31315, July 1, 2019 (FRL-9995-40)). The comment period lasted 60 days from July 1, 2019. Based on public comments and peer review comments received, EPA revised and issued the risk evaluation in September 2020 (85 FR 60456, September 25, 2020 (FRL-10014-87)). Since changing the risk determination to a whole chemical approach does not impact the underlying data and analysis presented in the risk characterization of the risk evaluation, information provided by the commentators that was not provided during the draft risk evaluation and not considered in the risk characterization, will be considered during risk management.

F. Other Comments.

Commenters indicated that the risk characterization did not adequately quantify HBCD's potential harm to children, tribal risk for Alaska native and arctic indigenous pregnant women and children, firefighters, disposal, legacy uses, fenceline communities. A commenter indicated that even a full ban on HBCD cannot be considered to be protective of risks from legacy use and associated disposal.

Other comments stated that if EPA did not reassess the conditions of use that do not present unreasonable risk, there is no basis for withdrawal of the associated orders. Others stated that there would be regulatory issues regardless because EPA has yet to finalize an amended risk management rule and resolve potential preemption concerns.

A commenter noted that, due to the highly regulated nature of HBCD on the international level, the chemical has been phased out of new production or manufacture of new replacement parts and additional regulation would be duplicative. One commenter stated that as legacy replacement parts are phased out of the automobile sector, HBCD will be cleared from trade channels and pose very little risk to workers and the general population.

A commenter suggested that EPA conducts another peer-review on the risk characterization section of the risk determination so that the lack of PPE use in the future can be thoroughly reviewed and assessed.

Another commenter said that the Federal Register Notice does not clearly identify the chemicals in HBCD which could cause future regulatory confusion when applying the whole chemical risk determination.

EPA Response: As previously explained in Ref. 9, EPA incorporated aggregate exposures covering all potential exposure routes for the general population and consumers in the final risk evaluation and now in the revised unreasonable risk determination. In addition, infants and subsistence fishers are identified as potentially exposed or susceptible subpopulations (PESS) and risks are reflected in the final risk evaluation. Finally, EPA explained how exposures to

firefighters were considered and acknowledges that firefighter exposure to HBCD is an uncertainty in the risk evaluation (see Section 2.4.1.15.5 of the Risk Evaluation). Fenceline communities living near disposal sites were included in the final risk evaluation as part of EPA's assessment of potential exposure routes for the general population. EPA added conditions of use for the activities it had initially excluded as legacy uses and associated disposals in the risk evaluation for HBCD. Exposure to HBCD from use, reuse, recycling, or disposal of discontinued products and articles is not excluded from the final risk evaluation.

Because EPA is finding that HBCD, as a whole chemical substance, presents unreasonable risk under the conditions of use, EPA is also withdrawing the TSCA section 6(i)(1) no unreasonable risk order issued in Section 5.4.1 of the 2020 HBCD risk evaluation. TSCA section 18(c)(3) defines the scope of federal preemption with respect to any final rule EPA issues under TSCA section 6(a). That provision provides that federal preemption of statutes, criminal penalties, and administrative actions applies to the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action the Administrator takes pursuant to TSCA section 6(a)] EPA reads this to mean that states are preempted from imposing requirements through statutes, criminal penalties, and administrative actions relating to any hazards, exposures, risks, and uses or conditions of use evaluated in the final risk evaluation and informing the unreasonable risk determination that EPA addresses in the TSCA section 6(a) rulemaking. For example, federal preemption applies even if EPA does not regulate in that final rule a particular COU, but that COU was evaluated in the final risk evaluation.

There is no change in the underlying scientific analysis of the September 2020 risk evaluation with regard to COUs that may relate to replacement parts. The revised risk determination identifies COUs that drive unreasonable risk from HBCD, which may include COUs that relate to replacement parts or articles. Under TSCA section 6(c)(2)(D), the consideration of replacement parts will take place during the risk management rulemaking stage, based on the risk evaluation findings. EPA acknowledges the comment about duplicative

regulation of HBCD, and encourages the commenter to submit specific comments along these lines during the future public comment period for the HBCD risk management rule.

The revised unreasonable risk determination for HBCD is based on the underlying risk assessments and risk characterization, in which EPA evaluated worker risk with and without PPE, and which were peer-reviewed by the SACC. No changes have been made to the peer reviewed risk assessments or risk characterization as a result of revisions to the risk determination for HBCD, and therefore EPA does not plan to conduct another round of peer review.

The Executive Summary in the final risk evaluation states that HBCD is often characterized as a mixture of mainly three diastereomers, which differ only in the spatial disposition of the atoms: Hexabromocyclododecane (CASRN 25637-99-4), 1,2,5,6,9,10-hexabromocyclododecane (CASRN 3194-55-6); and, 1,2,5,6-tetrabromocyclooctane (CASRN 3194-57-8). The revised unreasonable risk determination for HBCD applies to the cyclic aliphatic bromide cluster (HBCD) that includes all three chemicals. Any future proposed and final rule to address the unreasonable risk presented by HBCD will be for the HBCD cluster: Hexabromocyclododecane (CASRN 25637-99-4), 1,2,5,6,9,10-hexabromocyclododecane (CASRN 3194-55-6); and, 1,2,5,6-tetrabromocyclooctane (CASRN 3194-57-8).

IV. Revision of the September 2020 Risk Evaluation

A. Why is EPA proposing to revise the risk determination for the HBCD risk evaluation?

EPA is finalizing the revised risk determination for the HBCD risk evaluation pursuant to TSCA section 6(b) and consistent with Executive Order 13990, (Ref 2) and other Administration priorities (Refs. 1, 3, and 4). EPA is revising specific aspects of the first ten TSCA existing chemical risk evaluations in order to ensure that the risk evaluations better align with TSCA's objective of protecting health and the environment. For the HBCD risk evaluation, this includes: (1) making the risk determination in this instance based on the whole chemical approach instead of by individual conditions of use; and (2) emphasizing that EPA does not rely on the assumed

use of PPE when making the risk determination.

B. What are the revisions?

EPA is now finalizing the revised risk determination for the HBCD Risk Evaluation pursuant to TSCA section 6(b). Under the revised determination, EPA concludes that HBCD, as evaluated in the risk evaluation as a whole, presents an unreasonable risk of injury to health and environment under its conditions of use. This revision replaces the previous unreasonable risk determinations made for HBCD by individual conditions of use, supersedes the determinations (and withdraws the associated order) of no unreasonable risk for the conditions of use identified in the TSCA section 6(i)(1) no unreasonable risk order, and clarifies the lack of reliance on assumed use of PPE as part of the risk determination.

These revisions do not alter any of the underlying technical or scientific information that informs the risk characterization, and as such the hazard, exposure, and risk characterization sections are not changed. The discussion of the issues in this Notice and in the accompanying final revision to the risk determination supersede any conflicting statements in the prior executive summary from the HBCD risk evaluation and the response to comments document (Ref. 9).

In response to public comments, EPA is changing the name of the condition of use previously named *Import* to now be named *Manufacturing – Import* to clarify that manufacture also includes import, as defined by TSCA section 3(9). The revised unreasonable risk determination for HBCD also includes additional explanation of how the risk evaluation characterizes the applicable OSHA requirements, or industry or sector best practices, and also clarifies that no additional analysis was done and the risk determination is based on the risk characterization (Section 4) of the 2020 HBCD risk evaluation.

C. Will the revised risk determination be peer reviewed?

The risk determination (Section 5 of the Risk Evaluation) was not part of the scope of the Science Advisory Committee on Chemicals (SACC) peer review of the HBCD risk evaluation.

Thus, consistent with that approach, EPA did not conduct peer review of the final revised unreasonable risk determination for the HBCD risk evaluation because no technical or scientific changes were made to the hazard or exposure assessments or the risk characterization.

V. Order Withdrawing Previous Order Regarding Unreasonable Risk Determinations for Certain Conditions of Use

EPA is also issuing a new order to withdraw the TSCA Section 6(i)(1) no unreasonable risk order issued in Section 5.4.1 of the 2020 HBCD risk evaluation. This final revised risk determination supersedes the condition of use-specific no unreasonable risk determinations in the September 2020 HBCD risk evaluation. The order contained in section 5.5 of the revised risk determination (Ref. 8) withdraws the TSCA section 6(i)(1) order contained in section 5.4.1 of the September 2020 risk evaluation for HBCD. Consistent with the statutory requirements of section 6(a), the Agency will propose risk management actions to address the unreasonable risk determined in the HBCD risk evaluation.

VI. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. *Federal Register* (86 FR 7037, January 25, 2021).
2. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *Federal Register* (86 FR 7009, January 25, 2021).
3. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. *Federal*

Register (86 FR 7619, February 1, 2021).

4. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. *Federal Register* (86 FR 8845, February 10, 2021).

5. EPA. Proposed Rule; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. *Federal Register* (82 FR 7562, January 19, 2017) (FRL- 9957–75).

6. EPA. Final Rule; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. *Federal Register* (82 FR 33726, July 20, 2017) (FRL-9964–38).

7. EPA. Response to Public Comments to the revised Unreasonable Risk Determination for Cyclic Aliphatic Bromide Cluster (HBCD). June 2022.

8. EPA. Unreasonable Risk Determination for Cyclic Aliphatic Bromide Cluster (HBCD). June 2022.

9. EPA. Summary of External Peer Review and Public Comments and Disposition for Cyclic Aliphatic Bromide Cluster (HBCD), September 2020. Available at: <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0237-0069>.

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